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**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Parts 721**

**[EPA-HQ-OPPT-2007-0490; FRL-9912-87]**

**RIN 2070-AJ96**

**Certain Nonylphenols and Nonylphenol Ethoxylates; Significant New Use Rule**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Proposed rule.

**SUMMARY:** Under the Toxic Substances Control Act (TSCA), EPA is proposing a significant new use rule (SNUR) for 15 related chemical substances commonly known as nonylphenols (NP) and nonylphenol ethoxylates (NPE). For 13 NPs and NPEs, EPA is proposing to designate any use as a "significant new use," and for 2 additional NPs, EPA is proposing that any use other than use as an intermediate or use as an epoxy cure catalyst would constitute a "significant new use." Persons subject to these SNURs would be required to notify EPA at least 90 days before they manufacture (including import) or process any of these 15 chemical substances for a significant new use. The required notification would provide EPA with the opportunity to evaluate the new uses and protect against unreasonable risks, if any, from potential new exposures to NPs and NPEs, before that activity occurs.

**DATES:** Comments must be received on or before [*insert date 60 days after date of publication in the* **Federal Register**].

**ADDRESSES:** Submit your comments, identified by docket identification (ID) number EPA-HQ-OPPT-2007-0490, by one of the following methods:

• *Federal eRulemaking Portal*: *http://www.regulations.gov*. Follow the online

instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

• *Mail*: Document Control Office (7407M), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

• *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.html*. Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets*.

**FOR FURTHER INFORMATION CONTACT:** *For technical information regarding the SNUR, contact*: Jeffrey Taylor, Chemical Control Division (7405M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202)-564-8828; e-mail address*:* *taylor.jeffrey*@epa.gov.

*For general information, contact*: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554–1404; e-mail address: *TSCA-Hotline@epa.gov*.

**SUPPLEMENTARY INFORMATION:**

**I. Executive Summary**

*A. Does this Action Apply to Me?*

You may be potentially affected by these actions if you manufacture (including import) or process any of the chemical substances covered by this proposed SNUR. The North American

Industrial Classification System (NAICS) codes that are identified in this unit are not intended to be exhaustive, but rather provide a guide to help readers determine whether this rule applies to them. Potentially affected entities may include:

• Manufacturers (including importers) or processors of one or more of the subject chemical substances (North American Industrial Classification System (NAICS) codes 325 and 324110), e.g., chemical manufacturing and petroleum refineries.

• Surface active agent manufacturers (NAICS code 325613).

This action may also affect certain entities due to pre-existing import certification and export notification rules under TSCA. Persons who import any chemical substance governed by a final SNUR are subject to the TSCA section 13 (15 U.S.C. 2612) import certification requirements and the corresponding regulations at 19 CFR 12.118 through 12.127; see also 19 CFR 127.28. Those persons must certify that the shipment of the chemical substance complies with all applicable rules and orders under TSCA, including any SNUR requirements. The EPA policy in support of import certification appears at 40 CFR part 707, subpart B. In addition, any persons who export or intend to export a chemical substance that is the subject of this proposed rule on or after [*insert date 30 days after the date of publication in the* **Federal Register**] are subject to the export notification provisions of TSCA section 12(b) (15 U.S.C. 2611(b)) (see 40 CFR 721.20) and must comply with the export notification requirements in 40 CFR part 707, subpart D.

To determine whether you or your business may be affected by this action, you should carefully examine the applicability of provisions in 40 CFR 721.5. If you have any questions regarding the applicability of this action to a particular entity, consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

*B. What Is the Agency's Authority for Taking this Action?*

Section 5(a)(2) of TSCA (15 U.S.C. 2604(a)(2)) authorizes EPA to determine that a use of a chemical substance is a "significant new use." EPA must make this determination by rule after considering all relevant factors, including those listed in TSCA section 5(a)(2). Once EPA determines that a use of a chemical substance is a significant new use, TSCA section 5(a)(1)(B) requires persons to submit a significant new use notice (SNUN) to EPA at least 90 days before they manufacture or process the chemical substance for that use (15 U.S.C. 2604(a)(1)(B)). As described in Unit V., the general SNUR provisions are found at 40 CFR part 721, subpart A.

*C. What Action Is the Agency Taking?*

EPA is proposing a SNUR for 15 NPs and NPEs. EPA is proposing to designate any use of the 13 NPs and NPEs listed in Table 1 of Unit II.A. as a significant new use, and any use other than use as an intermediate or use as an epoxy cure catalyst as a significant new use of the 2 additional NPs listed in Table 2 of Unit II.A.

This proposed SNUR would apply to the uses that are not ongoing at the time of this proposed rule. Uses not ongoing at the time of the proposal would be designated significant new uses in the final SNUR. EPA is requesting public comment on this proposal, and specifically on whether the Agency has correctly identified the current and ongoing uses of the 15 NPs and NPEs covered by this proposed rule. EPA is particularly interested in whether anyone is currently using these chemicals in a manner that is not described in this proposal.

Persons subject to a SNUR would be required to notify EPA at least 90 days before commencing manufacture (including import) or processing of any of the subject chemical substances for a significant new use, consistent with the requirements at 40 CFR 721.25.

*D. Why Is the Agency Taking this Action?*

This proposed SNUR is necessary to ensure that EPA receives timely advance notice of any future manufacturing and processing of these chemical substances for the designated new uses to allow the Agency to evaluate any potential changes in human and environmental exposures. The rationale and objectives for this proposed SNUR are explained in Unit III.

*E. What are the Estimated Incremental Impacts of this Action?*

EPA has evaluated the potential costs of establishing SNUR reporting requirements for potential manufacturers and processors of the chemical substances included in this proposed rule. This analysis, which is available in the docket, is discussed in Unit IX., and is briefly summarized here. In the event that a SNUN is submitted, costs are estimated at approximately $8,589 per SNUN submission for large business submitters and $6,189 for small business submitters. These estimates include the cost to prepare and submit the SNUN and the payment of a user fee. In addition, for persons exporting a substance that is the subject of a SNUR, a one-time notice must be provided for the first export or intended export to a particular country, which is estimated to cost less than $100 on average per notification.

Since EPA is unable to predict whether anyone might engage in future activities that would require reporting, potential total costs are estimated to range from $0 to less than $10,000.

## II. Chemical Substances Subject to this Proposed Rule

*A. What Chemicals Are Subject to this Proposed SNUR?*

This proposed SNUR would apply to the 15 NPs and NPEs in Tables 1 and 2 of this unit. To ascertain whether these chemicals are currently in commerce, EPA analyzed uses that are described in Unit II.B, and also reviewed the most recent data from EPA's Chemical Data Reporting (CDR) database (Ref. 1). Twelve of the 13 linear NPs and NPEs in Table 1 of this unit are not reported on CDR. One NPE chemical, known as poly(oxy-1,2-ethanediyl),

α(nonylphenyl)-ω–hydroxy- (CASRN 9016-45-9), also listed in Table 1 of this unit, was reported to the 2012 CDR. EPA believes, however, that the manufacturer incorrectly identified the chemical in its CDR report, and that, in fact, poly(oxy-1,2-ethanediyl), α(nonylphenyl)-ω–hydroxy- (CASRN 9016-45-9) is not currently manufactured for any use. The manufacturer reported the chemical identity as a linear form of NPE, but the available information indicates that the manufacturer should have reported the identity as a branched NPE. Based on chemical engineering literature and industry expert sources, as described later in this unit, EPA's understanding is that only branched forms of NP and NPE chemical substances are currently manufactured for commercial purposes. The two chemical substances listed in Table 2 were both reported to the 2012 CDR and are used as an intermediate and as an epoxy cure catalyst.

**Table 1. NPs and NPEs for which Any Use Is a Significant New Use**

| Chemical Name | Chemical Abstracts Index Name | Chemical Abstracts Service Registry No. (CASRN) | NP or NPE |
|---|---|---|---|
| 4-nonylphenol | Phenol, 4-nonyl- | 104-40-5 | NP |
| 2-[2-[2-[2-(4-nonylphenoxy)ethoxy]ethoxy]ethoxy]ethanol | Ethanol, 2-[2-[2-[2-(4-nonylphenoxy)ethoxy]ethoxy]ethoxy]- | 7311-27-5 | NPE |
| α(Nonylphenyl)-ω–hydroxy-poly(oxy-1,2-ethanediyl) | Poly(oxy-1,2-ethanediyl), α(nonylphenyl)-ω–hydroxy- | 9016-45-9 | NPE |
| 2-[2-(4-nonylphenoxy)ethoxy]ethanol | Ethanol, 2-[2-(4-nonylphenoxy)ethoxy]- | 20427-84-3 | NPE |
| Nonylphenol | Phenol, nonyl- | 25154-52-3 | NP |
| α–(4-Nonylphenyl)-ω–hydroxy-poly(oxy-1,2-ethanediyl) | Poly(oxy-1,2-ethanediyl), α–(4-nonylphenyl)-ω–hydroxy- | 26027-38-3 | NPE |
| 2-[2-[2-[2-[2-[2-[2-[2-[2-(Nonylphenoxy)ethoxy]ethoxy]ethoxy]ethoxy]ethoxy]ethoxy]ethoxy]ethanol | 3,6,9,12,15,18,21,24-Octaoxahexacosan-1-ol, 26-(nonylphenoxy)- | 26571-11-9 | NPE |
| 2-[2-(Nonylphenoxy)ethoxy]ethanol | Ethanol, 2-[2-(nonylphenoxy)ethoxy]- | 27176-93-8 | NPE |
| 2-[2-[2-[2-[2-[2-[2-[2-(nonylphenoxy)ethoxy]ethoxy]ethoxy]ethoxy]ethoxy]ethoxy]ethanol | 3,6,9,12,15,18,21-Heptaoxatricosan-1-ol, 23-(nonylphenoxy)- | 27177-05-5 | NPE |
| 2-[2-[2-[2-[2-[2-[2-[2-[2-[2-(nonylphenoxy)ethoxy]ethoxy]ethoxy]ethoxy]ethoxy]ethoxy]ethoxy]ethoxy]ethanol | 3,6,9,12,15,18,21,24,27-Nonaoxanonacosan-1-ol, 29-(nonylphenoxy)- | 27177-08-8 | NPE |
| 2-(Nonylphenoxy)ethanol | Ethanol, 2-(nonylphenoxy)- | 27986-36-3 | NPE |
| α–(Isononylphenyl)-ω–hydroxy-poly(oxy-1,2-ethanediyl) | Poly(oxy-1,2-ethanediyl), α–(isononylphenyl)-ω–hydroxy- | 37205-87-1 | NPE |

| | | | |
|---|---|---|---|
| α–(2-Nonylphenyl)-ω–hydroxy-poly(oxy-1,2-ethanediyl), | Poly(oxy-1,2-ethanediyl), α–(2-nonylphenyl)-ω–hydroxy- | 51938-25-1 | NPE |

**Table 2. NPs for which Any Use Other Than as an Intermediate or Epoxy Cure Catalyst Is a Significant New Use**

| Chemical Name | Chemical Abstracts Index Name | Chemical Abstracts Service Registry No. (CASRN) | NP or NPE |
|---|---|---|---|
| 4-nonylphenol, branched | Phenol, 4-nonyl-, branched | 84852-15-3 | NP |
| 2-nonylphenol, branched | Phenol, 2-nonyl-, branched | 91672-41-2 | NP |

NPs and NPEs consist of a nine carbon nonyl group in either branched or linear form bound at various positions *(ortho, meta, or para)* around a phenol ring. Nonylphenol is produced by the acid-catalyzed reaction of nonene and phenol. The degree of branching of the nonene used in that reaction determines the degree of branching in the product NP. EPA's understanding of the chemistry and engineering of commercial NP production is that it starts with nonene that is produced by acid-catalyzed propylene trimerization. Nonene produced in this way is a complex mixture of highly branched alkenes and contains negligible amounts of linear olefins. Manufacturers combine this highly branched nonene with phenol in an acid-catalyzed reaction. This reaction pathway is described in the literature and industry publications. For example, the Kirk-Othmer Encyclopedia of Chemical Technology states, "All commercially produced PNP [*para*-nonylphenol, or 4-nonylphenol] is made from nonene based on the trimerization of propylene" (and therefore is highly branched) (Ref. 2). Similarly, industry assessments state that commercial nonene (used to make NP) does not contain linear $C_9H_{18}$ alpha-olefin; rather, it is a complex mixture of highly branched, predominantly nine-carbon olefins known as propylene trimers (Ref. 3). Additionally, some industrial sources assert that linear NP is a laboratory chemical substance that is not used in commerce and is not a degradant found in the environment

(Ref. 4).

During the development of a testing consent order on 4-nonylphenol (Ref. 5), the Alkylphenols and Ethoxylates Panel of the American Chemistry Council (ACC) confirmed EPA's assessment, stating that, as it is currently manufactured, nonylphenol is a substance comprising mostly branched C9-alkyl phenols and is best represented by 4-nonylphenol, Chemical Abstract Services Registry Number (CASRN) 84852-15-3.

*B. What Are the Uses and Production Levels of the NPs and NPEs Covered by this Proposed SNUR?*

Branched 4-nonylphenol (CASRN 84852-15-3), in Table 2 of this unit, was reported to the 2012 CDR at 100-500 million pounds production volume. Branched 2-nonylphenol (CASRN 91672-41-2), also in Table 2 of this unit, was reported to the 2012 CDR at 1-10 million pounds production volume.

Linear NPE, poly(oxy-1,2-ethanediyl), α(nonylphenyl)-ω–hydroxy- (CASRN 9016-45-9), in Table 1 of this unit, was reported to the 2012 CDR with a 2011 production volume ranging from 10 million to 50 million pounds. As described earlier in this unit, EPA believes that this linear NPE was incorrectly identified and the manufacturer was in fact producing a branched NPE (i.e., another chemical entirely). The other 12 linear NPs and NPEs have no reported production volume on the 2012 CDR. Nonylphenol (CASRN 25154-52-3), in Table 1 of this unit, was initially reported to the 2012 CDR, but EPA understands that the chemical should have been reported as either branched NP CASRN 84852-15-3 or branched NP CASRN 91672-41-2. Companies who reported nonylphenol with CASRN 25154-52-3 to the 2012 CDR have corrected their reports, which results in the chemical having no production volume on the 2012 CDR.

Certain NPs are used primarily as intermediates to produce other chemical substances,

notably NPEs. NPEs are manufactured by reacting the hydroxyl group (-OH) of NP with ethylene oxide in an iterative process, forming a combination of NPEs of various chain lengths, typically ranging from 4 to 80 ethoxylate (EO) groups. The commonly-used NPEs have chain lengths averaging 8 to 12 EO groups, and commercial NPEs will contain NPEs of various chain lengths. Different degrees of ethoxylation impart different properties, which make the chemical substances useful in a variety of applications.

EPA accessed information from the 2012 CDR database, along with the Household Products Database and the Consumer Product Information Database, in order to analyze use of NPs and NPEs broadly within U.S. commerce (Refs. 1, 6, and 7). Reported NPs are used as intermediates to create NPEs, and they are also used as epoxy cure catalysts. Reported NPEs are used in a wide range of applications, and can be found in consumer products related generally to home care, personal hygiene, automotive, and lawn care. Specifically, the NPEs are used in: Laundry detergents, engine and battery cleaners, all-purpose cleaners, paints, metal polishers, stain pretreatment, sealants, paint/varnish strippers, wallpaper removers, hand cleaners, floor strippers, disinfectant/mold inhibitors, concrete cleaners, tile/grout cleaners, degreasers, brush cleaners, tile adhesives, and wood finishes (Refs. 1, 6, 7, 8, and 9).

*C. What Are the Potential Environmental Effects of, and Routes and Sources of Exposure to, the NPs and NPEs Covered by this Proposed SNUR?*

NPs and NPEs with only one or two EO groups are persistent, low-to-moderately bioaccumulative, and highly toxic to aquatic organisms. In general, toxicity to environmental organisms increases with decreasing degrees of ethoxylation for nonylphenolic compounds, with NPs being most toxic. NPEs with greater degrees of ethoxylation, while less toxic, degrade to the more toxic and persistent, less ethoxylated forms of these chemical substances in the

environment. Available data indicate that these chemical substances are highly toxic to fish and invertebrates, causing lethality on an acute basis and effects on survival, growth, development, metabolism, reproduction, and fecundity with low-level chronic exposures (Refs. 10 and 11). EPA has established water quality criteria for NPs of 6.6 microgram per litre (μg/L) for acute exposures and 1.7 μg/L for chronic exposures (Ref. 12). EPA has not established water quality criteria for NPEs. Environment Canada has also established a concern level for NPs (and NPEs, as expressed in NP toxic equivalency units) of 0.7 μg/L for indefinitely chronic exposures (Refs. 12 and 13). EPA recognizes that NPs and NPEs may be endocrine bioactive (Refs. 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, and 24).

Certain NPs and NPEs are produced in large volumes, with uses in a wide range of applications (e.g., home care, personal hygiene, automotive, and lawn care consumer products) that lead to widespread releases to the aquatic environment. NPEs are clear to light orange oily liquids or waxy solids, and are considered to be chemically stable and unreactive (Ref. 25). NPEs show a gradual, linear increase in water solubility with greater degree of ethoxylation (e.g., the reported water solubility of NP with five ethoxyl groups attached, NP5EO, is 9.48 mg/L; and the reported water solubility of NP with twelve ethoxyl groups attached, NP12EO, is 42.5 mg/L) (Refs. 26 and 27). The most important processes affecting the persistence, distribution, and bioavailability of nonylphenolic substances in the environment are biodegradation and sorption (Refs. 28, 29, 30, and 31). NPEs with greater degrees of ethoxylation degrade to less ethoxylated forms of these chemical substances in the environment. NPEs with fewer degrees of ethoxylation continue to degrade slowly to NPs. NPs, especially highly branched NPs, degrade most slowly (Refs. 8 and 9). The aerobic and anaerobic biodegradation of NPEs occurs through different reaction pathways resulting in the formation of different degradation products. Under

aerobic conditions, evidence shows that carboxylated NPEs (NPECs) of higher ethoxamers are quickly formed (e.g., NP9EC from NP9EO), followed by shortening of the ethoxylate chain through the deethoxylation pathway (e.g., NP2EC from NP9EC), and oxidation of the nonyl chain to form dicarboxylated derivatives. Such dicarboxylated products are referred to as carboxylated nonylphenyl ethoxycarboxylates, or CAPECs. Under anaerobic conditions, the dominant degradation pathways for NPEs is most likely deethoxylation (e.g., NP1EO and NP2EO from higher ethoxamers) and *O*-dealkylation (e.g., NP from NP2EO) (Refs. 32 and 33). The resistance of NPs to further degradation under anaerobic conditions is a contributing factor to their accumulation in sludge.

Ecological receptors can potentially be significantly exposed to NPs and NPEs under current manufacturing practices as a result of surface water discharges from facilities that manufacture products containing NPs or NPEs (Ref. 34). Once released into the environment, NPs and NPEs tend to partition to sediments and accumulate (Ref. 35). Thus, even if the discharges decrease, or cease, environmental exposures can continue.

A range of levels of NPs and NPEs have been measured in surface water and sediment in U.S. waters. Certain NPEs are widely used in industrial processes and cleaning products, including industrial laundry detergents, and are frequently found in wastewater and sewage treatment plant effluents, with subsequent discharge into the environment (Ref. 36). Localized monitoring studies have found surface waters near industrial discharges contained NPs in concentrations ranging from 2 to 1,617 μg/L (Ref. 37) and NP concentrations in more diffuse surface water and sediments in the Great Lakes ranging from 0.01 to 0.92 μg/L for water and 37 to 300 μg/g for sediments (Ref. 36). In surface water samples collected along the Ohio River, total NPEs ranged from 0.13 to 1.0 μg/L for water, from 250 to 1,020 μg/g for sediments, and

from 32 to 920 μg/g for carp, a bottom dwelling fish (Ref. 38). Some of the measured surface water concentrations, particularly those near industrial discharges, exceeded the EPA Water Quality Criteria set for freshwater species living in the water column. Nonylphenol has also been found in Minnesota lakes, with maximum concentrations reaching 20 ng/L (Ref. 39). NPs and NPEs in freshwater and saltwater ecosystems can potentially cause ecological effects on all trophic levels of aquatic species exposed to them (Ref. 12).

**III. Rationale and Objective**

*A. Rationale*

NPs and short-chain NPE ethoxymers (NP with one ethoxyl group attached, NP1EO, and NP with two ethoxyl groups attached, NP2EO) are persistent, low-moderately bioaccumulative, and highly toxic to aquatic organisms. Available data indicate that these substances are highly toxic to fish and invertebrates, causing lethality on an acute basis and effects on survival, growth, development, metabolism, reproduction, and fecundity with low-level chronic exposures (Refs. 10 and 11). Exposure occurs through industrial and wastewater discharges that ultimately reach surface waters and sediments. NPs and NPEs can potentially cause ecological effects on all trophic levels of aquatic species exposed to them in freshwater and saltwater ecosystems (Ref. 12).

Of the 13 linear NPs and NPEs listed in Table 1 of Unit II.A., 12 of the chemical substances were not reported to the 2012 CDR. One of these 13 substances was reported to the 2012 CDR, but as discussed in Unit II.B., the available information indicates that the chemical substance is not currently being manufactured or is otherwise used or distributed in commerce. The two branched NPs listed in Table 2 of Unit II.A. are not in use except as intermediates and epoxy cure catalysts. Based on the reasonably anticipated manner and methods of

manufacturing, processing, distribution in commerce, and disposal of these chemical substances, EPA is concerned that future manufacturing or processing of these 15 NP and NPE chemicals could have the potential to significantly increase the magnitude and duration of environmental exposures. As previously discussed, based on current use and manufacturing practices, NPEs are frequently found in wastewater and sewage treatment plant effluents, with subsequent discharge into the environment. EPA has no reason to anticipate that future manufacturing practices and uses are likely to result in lower discharges.

Accordingly, EPA has determined that individual evaluation of the activities associated with those new uses is warranted to allow the Agency to determine whether any controls are necessary before such manufacturing (including importing) or processing starts or resumes. The required notification provided by a SNUN would provide EPA with the opportunity to evaluate the new uses and protect against unreasonable risks, if any, from potential new exposures to NPs and NPEs.

Consistent with EPA's past practice for issuing SNURs under TSCA section 5(a)(2), EPA's decision to propose a SNUR for a particular chemical use need not be based on an extensive evaluation of the hazard, exposure, or potential risk associated with that use. Rather, the Agency action is based on EPA's determination that if the use begins or resumes, it may present a risk that EPA should evaluate under TSCA before the manufacturing or processing for that use begins. Since the new use does not currently exist, deferring a detailed consideration of potential risks or hazards related to that use is an effective use of resources. If a person decides to begin manufacturing or processing the chemical substance for the use, the notice to EPA allows the Agency to evaluate the use according to the specific parameters and circumstances surrounding that intended use.

*B. Objective*

Based on the considerations in Unit IV.A., EPA wants to achieve the following objectives through this action:

1. EPA would receive notice of any person's intent to manufacture (including import) or process the 15 NPs and NPEs for the described significant new uses before that activity begins.

2. EPA would have an opportunity to review and evaluate any data submitted in a SNUN before the notice submitter begins manufacturing (including importing) or processing of the 15 NPs and NPEs for the described significant new use.

3. EPA would be able to regulate prospective manufacturers (including importers) or processors of these chemical substances before the described significant new use of the chemical substance occurs, provided that regulation is warranted pursuant to TSCA sections 5(e), 5(f), 6, or 7.

**IV. Significant New Use Determination**

Section 5(a)(2) of TSCA states that EPA's determination that a use of a chemical substance is a significant new use must be made after consideration of all relevant factors including:

1. The projected volume of manufacturing and processing of a chemical substance.

2. The extent to which a use changes the type or form of exposure of human beings or the environment to a chemical substance.

3**.** The extent to which a use increases the magnitude and duration of exposure of human beings or the environment to a chemical substance.

4. The reasonably anticipated manner and methods of manufacturing, processing, distribution in commerce, and disposal of a chemical substance.

In addition to these factors enumerated in TSCA section 5(a)(2), the statute authorizes EPA to consider any other relevant factors.

To determine what would constitute a significant new use of the 15 NPs and NPEs subject to this proposed rule**,** EPA considered relevant information about the toxicity of the substances, exposures, environmental releases, and the four factors listed in section 5(a)(2) of TSCA.

EPA has preliminarily determined that any use of the 13 linear NPs and NPEs listed in Table 1 of Unit II.A. is a significant new use. EPA has also preliminarily determined that any use of the branched NPs listed in Table 2 of Unit II.A., other than use as an intermediate or use as an epoxy cure catalyst, is a significant new use. As discussed previously in this unit, EPA is concerned that future manufacturing or processing of these 15 NP and NPE chemicals could have the potential to significantly increase the magnitude and duration of environmental exposures, and EPA has no reason to anticipate that future manufacturing practices and uses are likely to result in lower discharges.

**V. Applicability of General Provisions**

General provisions for SNURs appear under 40 CFR part 721, subpart A. These provisions describe persons subject to the rule, recordkeeping requirements, exemptions to reporting requirements, and applicability of the rule to uses occurring before the effective date of the final rule.

Provisions relating to user fees appear at 40 CFR part 700. According to 40 CFR 721.1(c), persons subject to SNURs must comply with the same notice requirements and EPA regulatory procedures as submitters of Premanufacture Notices (PMNs) under TSCA section 5(a)(1)(A). In particular, these requirements include the information submission requirements of

TSCA section 5(b) and 5(d)(1), the exemptions authorized by TSCA section 5(h)(1), (h)(2), (h)(3), and (h)(5), and the regulations at 40 CFR part 720. Once EPA receives a SNUN, EPA may take regulatory action under TSCA sections 5(e), 5(f), 6, or 7 to control the activities on which it has received the SNUN. If EPA does not take action, EPA is required under TSCA section 5(g) to explain in the **Federal Register** its reasons for not taking action.

Persons who export or intend to export a chemical substance that is the subject of a proposed or final SNUR are subject to the export notification provisions of TSCA section 12(b). The regulations that interpret TSCA section 12(b) appear at 40 CFR part 707, subpart D. Persons who import a chemical substance identified in a final SNUR are subject to the TSCA section 13 import certification requirements, codified at 19 CFR 12.118 through 12.127; see also 19 CFR 127.28. Such persons must certify that the shipment of the chemical substance complies with all applicable rules and orders under TSCA, including any SNUR requirements. The EPA policy in support of import certification appears at 40 CFR part 707, subpart B.

**VI. Applicability of the Rule to Uses Occurring before Effective Date of the Final Rule**

As discussed in the **Federal Register** of April 24, 1990 (55 FR 17376) (FRL-3658-5), EPA has decided that the intent of section 5(a)(1)(B) of TSCA is best served by designating a use as a significant new use as of the date of publication of the proposed rule rather than as of the effective date of the final rule. If uses that had begun after the proposed rule was published were considered ongoing rather than new, any person could defeat the SNUR by initiating the significant new use before the final rule was issued. Therefore, EPA designates [*insert date of publication of the proposed rule in the* **Federal Register**] as the cutoff date for determining whether any of the uses that are the subject of this proposal are ongoing. Persons who begin commercial manufacture or processing of the chemical substances for a significant new use

identified as of that date would have to cease any such activity upon the effective date of the final rule. To resume their activities, these persons would have to first comply with all applicable SNUR notification requirements and wait until the notice review period, including any extensions, expires. If such a person met the conditions of advance compliance under 40 CFR 721.45(h), the person would be considered exempt from the requirements of the SNUR. Consult the **Federal Register** final rule of April 24, 1990 for a more detailed discussion of the cutoff date for ongoing uses.

**VII. Test Data and Other Information**

EPA recognizes that TSCA section 5 does not usually require developing any particular test data before submission of a SNUN. There are two exceptions:

- Development of test data is required where the chemical substance subject to the SNUR is also subject to a test rule under TSCA section 4 (see TSCA section 5(b)(1)); and
- Development of test data may be necessary where the chemical substance has been listed under TSCA section 5(b)(4) (see TSCA section 5(b)(2)).

In the absence of a section 4 test rule or a section 5(b)(4) listing covering the chemical substance, persons are required to submit only test data in their possession or control and to describe any other data known to or reasonably ascertainable by them (15 U.S.C. 2604(d); 40 CFR 721.25, and 40 CFR 720.50). However, as a general matter, EPA recommends that SNUN submitters include data that would permit a reasoned evaluation of risks posed by the chemical substance during its manufacture, processing, use, distribution in commerce, or disposal. EPA encourages persons to consult with the Agency before submitting a SNUN. As part of this optional pre-notice consultation, EPA would discuss specific data that may be useful in evaluating a significant new use. SNUNs submitted for significant new uses without any test data may

increase the likelihood that EPA will take action under TSCA section 5(e) to prohibit or limit activities associated with this chemical substance.

SNUN submitters should be aware that EPA will be better able to evaluate SNUNs that provide detailed information on:

1. Human exposure and environmental releases that may result from the significant new uses of the chemical substance,

2. Potential benefits of the chemical substance, and

3. Information on risks posed by the chemical substances compared to risks posed by potential substitutes.

**VIII. SNUN Submissions**

EPA recommends that submitters consult with the Agency prior to submitting a SNUN to discuss what data may be useful in evaluating a significant new use. Discussions with the Agency prior to submission can afford ample time to conduct any tests that might be helpful in evaluating risks posed by the substance. According to 40 CFR 721.1(c), persons submitting a SNUN must comply with the same notice requirements and EPA regulatory procedures as persons submitting a PMN, including submission of test data on health and environmental effects as described in 40 CFR 720.50. SNUNs must be submitted on EPA Form No. 7710-25, generated using e-PMN software, and submitted to the Agency in accordance with the procedures set forth in 40 CFR 721.25 and 40 CFR 720.40. E-PMN software is available electronically at *http://www.epa.gov/opptintr/newchems*.

**IX. Economic Analysis**

*A. SNUNs*

EPA has evaluated the potential costs of establishing SNUR reporting requirements for

potential manufacturers and processors of the chemical substance included in this proposed rule (Ref. 40). In the event that a SNUN is submitted, costs are estimated at approximately $8,589 per SNUN submission for large business submitters and $6,189 for small business submitters. These estimates include the cost to prepare and submit the SNUN, and the payment of a user fee. Businesses that submit a SNUN would be subject to either a $2,500 user fee required by 40 CFR 700.45(b)(2)(iii), or, if they are a small business with annual sales of less than $40 million when combined with those of the parent company (if any), a reduced user fee of $100 (40 CFR 700.45(b)(1)). EPA's complete economic analysis is available in the public docket for this proposed rule (Ref. 40).

*B. Export Notification*

Under TSCA section 12(b) and the implementing regulations at 40 CFR part 707, subpart D, exporters must notify EPA if they export or intend to export a chemical substance or mixture for which, among other things, a rule has been proposed or promulgated under TSCA section 5. For persons exporting a substance that is the subject of a SNUR, a one-time notice must be provided for the first export or intended export to a particular country. The total costs of export notification will vary by chemical substance, depending on the number of required notifications (i.e., the number of countries to which the chemical substance is exported). EPA is unable to make any estimate of the likely number of export notifications for the chemical substance covered in this proposed SNUR.

**X. Alternatives**

Before proposing the SNUR, EPA considered the following alternative regulatory actions:

*A. Promulgate a TSCA Section 8(a) Reporting Rule*

Under a TSCA section 8(a) rule, EPA could, among other things, generally require persons to report information to the Agency when they intend to manufacture (including import) or process a listed chemical substance for a specific use or any use. However, for the 15 NPs and NPEs subject to this proposed rule, the use of TSCA section 8(a) rather than SNUR authority would have several limitations. First, if EPA were to require reporting under TSCA section 8(a) reporting for new uses instead of TSCA section 5(a), then EPA would not have the opportunity to review human and environmental hazards and exposures associated with the proposed significant new use and, if necessary, take immediate follow-up regulatory action under TSCA sections 5(e) or 5(f) to prohibit or limit the activity before it begins. In addition, EPA may not receive important information from small businesses because such firms generally are exempt from TSCA section 8(a) reporting requirements. In view of the level of environmental concerns about the 15 NPs and NPEs, EPA believes that a TSCA section 8(a) rule for this substance would not meet EPA's regulatory objectives.

*B. Regulate NPs and NPEs under TSCA Section 6*

Under TSCA section 6, EPA may regulate a chemical substance if "the Administrator finds that there is a reasonable basis to conclude that the manufacture, processing, distribution in commerce, use or disposal of a chemical substance or mixture . . . presents or will present an unreasonable risk of injury to health or the environment" (TSCA section 6(a)). Because EPA believes that the 13 NP and NPE chemical substances listed in Table 1 of Unit II.A. are not being used and the 2 NPs listed in Table 2 of Unit II.A. are not being used other than as an intermediate or epoxy cure catalyst, EPA concluded that risk management action under TSCA section 6 is not warranted at this time. EPA believes that this proposed SNUR would allow the Agency to effectively address concerns surrounding any proposed significant new use, should they arise, by

requiring prior notice of the use and allowing EPA a 90-day review period in which EPA would evaluate the use and could take action, as appropriate, under TSCA sections 5(e), 5(f), 6, or 7 to control the activities on which it has received the SNUN.

## XI. Request for Comment

*A. Do You Have Comments or Information About Ongoing Uses?*

EPA welcomes comment on all aspects of this proposed rule. EPA based its understanding of the use profile of these chemical substances on the 2012 CDR submissions, engineering literature, and communications with industry representatives. To confirm EPA's understanding, the Agency is requesting public comment on all aspects of this proposed rule, including the commercial production of linear forms of NPs and NPEs, as well as any ongoing uses of the subject chemical substances.

*B. What Should I Consider as I Prepare my Comments for EPA?*

1. *Submitting CBI.* Do not submit this information to EPA through regulations.gov or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD ROM that you mail to EPA, mark the outside of the disk or CD ROM as CBI and then identify electronically within the disk or CD ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When submitting comments, remember to:

i. Identify the document by docket ID number and other identifying information (subject heading, **Federal Register** date, and page number).

ii. Follow directions. The Agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.

iii. Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.

iv. Describe any assumptions and provide any technical information and/or data that you used.

v. If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.

vi. Provide specific examples to illustrate your concerns and suggest alternatives.

vii. Explain your views as clearly as possible, avoiding the use of profanity or personal threats.

viii. Make sure to submit your comments by the comment period deadline identified.

**XII. References**

The following is a listing of the documents that are specifically referenced in this document. The docket includes these documents and other information considered by EPA, including documents that are referenced within the documents that are in the docket, even if the referenced document is not physically located in the docket. For assistance in locating these other documents, please consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

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## XIII. Statutory and Executive Order Reviews

### *A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review*

The Office of Management and Budget (OMB) has determined that is proposed SNUR is not a "significant regulatory action," under section 3(f) of Executive Order 12866 (58 FR 51735, October 4, 1993). Accordingly, this action was not submitted to OMB for review under Executive Order 12866 and 13563 (76 FR 3821, January 21, 2011).

### *B. Paperwork Reduction Act (PRA)*

This action does not impose any new information collection burden under the PRA, 44 U.S.C. 3501 *et seq*. Burden is defined in 5 CFR 1320.3(b). The information collection activities associated with existing chemical SNURs are already approved by OMB under OMB control number 2070-0038 (EPA ICR No. 1188); and the information collection activities associated with export notifications are already approved by OMB under OMB control number 2070-0030 (EPA ICR No. 0795). If an entity were to submit a SNUN to the Agency, the annual burden is estimated to be less than 100 hours per response, and the estimated burden for an export

notifications is less than 1.5 hours per notification. In both cases, burden is estimated to be reduced for submitters who have already registered to use the electronic submission system.

*C. Regulatory Flexibility Act (RFA)*

Pursuant to section 605(b) of the RFA, 5 U.S.C. 601 *et seq*., the Agency hereby certifies that promulgation of this SNUR would not have a significant economic impact on a substantial number of small entities. The rationale supporting this conclusion is as follows.

A SNUR applies to any person (including small or large entities) who intends to engage in any activity described in the rule as a "significant new use." By definition of the word "new" and based on all information currently available to EPA, it appears that no small or large entities presently engage in such activity. Since this SNUR will require a person who intends to engage in such activity in the future to first notify EPA by submitting a SNUN, no economic impact will occur unless someone files a SNUN to pursue a significant new use in the future or forgoes profits by avoiding or delaying the significant new use. Although some small entities may decide to conduct such activities in the future, EPA cannot presently determine how many, if any, there may be. However, EPA's experience to date is that, in response to the promulgation of SNURs covering over 1,000 chemical substances, the Agency receives only a handful of notices per year. During the six year period from 2005-2010, only three submitters self-identified as small in their SNUN submission. EPA believes the cost of submitting a SNUN is relatively small compared to the cost of developing and marketing a chemical new to a firm and that the requirement to submit a SNUN generally does not have a significant economic impact.

Therefore, EPA has determined that the potential economic impact of complying with this SNUR is not expected to be significant or adversely impact a substantial number of small entities. In a SNUR that published as a final rule on August 8, 1997 (62 FR 42690) (FRL-5735-

4), the Agency presented its general determination that proposed and final SNURs are not expected to have a significant economic impact on a substantial number of small entities, which was provided to the Chief Counsel for Advocacy of the Small Business Administration.

*D. Unfunded Mandates Reform Act (UMRA)*

Based on EPA's experience with proposing and finalizing SNURs, State, local, and Tribal governments have not been impacted by these rulemakings, and EPA does not have any reason to be of the opinion that any State, local, or Tribal government would be impacted by this rulemaking. As such, EPA has determined that this regulatory action would not impose any enforceable duty, contain any unfunded mandate, or otherwise have any effect on small governments subject to the requirements of sections 202, 203, 204, or 205 of UMRA, 2 U.S.C. 1531-1538.

*E. Executive Order 13132: Federalism*

This action will not have a substantial direct effect on States, on the relationship between national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999).

*F. Executive Order 13175: Consultation and Coordination with Indian Tribal Governments*

This proposed rule does not have Tribal implications because it is not expected to have any effect (i.e., there will be no increase or decrease in authority or jurisdiction) on Tribal governments, on the relationship between the Federal government and the Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes. Thus, the requirements of Executive Order 13175 (65 FR 67249, November 9, 2000), do not apply to this rulemaking.

*G. Executive Order 13045*: *Protection of Children from Environmental Health Risks and Safety Risks*

This action is not subject to Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997), because this action is not intended to address environmental health or safety risks affecting children.

*H. Executive Order 13211: Actions that Significantly Affect Energy Supply, Distribution, or Use*

This proposed rule is not subject to Executive Order 13211 (66 FR 28355, May 22, 2001), because this action is not expected to affect energy supply, distribution, or use.

*I. National Technology Transfer and Advancement Act (NTTAA)*

Since this action does not involve any technical standards, section 12(d) of the NTTAA, 15 U.S.C. 272 note, does not apply to this action.

*J. Executive Order 12898: Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations*

This proposed rule does not entail special consideration of environmental justice related issues as delineated by Executive Order 12898 (59 FR 7629, February 16, 1994) because EPA has determined that this action will not have disproportionately high and adverse human health or environmental effects on minority or low-income populations. This action does not affect the level of protection provided to human health or the environment.

**List of Subjects in 40 CFR Part 721**

Environmental protection, Chemicals, Hazardous substances, Reporting and recordkeeping requirements.

Dated: September 24, 2014.

Wendy C. Hamnett,

*Director, Office of Pollution Prevention and Toxics.*

Therefore, it is proposed that 40 CFR chapter I be amended as follows:

**PART 721--[AMENDED]**

1. The authority citation for part 721 continues to read as follows:

**Authority:** 15 U.S.C. 2604, 2607, and 2625(c).

2. Add § 721.10765 to subpart E to read as follows**:**

**§ 721.10765 Nonylphenols and nonylphenol ethoxylates.**

(a) *Chemical substances and significant new uses subject to reporting*. (1) The chemical substances listed in Table 1 and Table 2 of this section are subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) For the chemical substances listed in Table 1 of this section, any use.

(ii) For the chemical substances listed in Table 2 of this section, any use other than as an intermediate or an epoxy cure catalyst.

**Table 1: NP and NPE Chemical Substances Subject to Reporting Any Use**

| Chemical Name | Chemical Abstracts Index Name | Chemical Abstracts Service Registry No. (CASRN) | NP or NPE |
|---|---|---|---|
| 4-nonylphenol | Phenol, 4-nonyl- | 104-40-5 | NP |
| 2-[2-[2-[2-(4-nonylphenoxy)ethoxy]ethoxy]ethoxy]ethanol | Ethanol, 2-[2-[2-[2-(4-nonylphenoxy)ethoxy]ethoxy]ethoxy]- | 7311-27-5 | NPE |
| α(Nonylphenyl)-ω–hydroxy-poly(oxy-1,2-ethanediyl) | Poly(oxy-1,2-ethanediyl), α(nonylphenyl)-ω–hydroxy- | 9016-45-9 | NPE |
| 2-[2-(4-nonylphenoxy)ethoxy]ethanol | Ethanol, 2-[2-(4-nonylphenoxy)ethoxy]- | 20427-84-3 | NPE |
| Nonylphenol | Phenol, nonyl- | 25154-52-3 | NP |
| α–(4-Nonylphenyl)-ω–hydroxy-poly(oxy-1,2-ethanediyl) | Poly(oxy-1,2-ethanediyl), α–(4-nonylphenyl)-ω–hydroxy- | 26027-38-3 | NPE |
| 2-[2-[2-[2-[2-[2-[2-[2-[2-(Nonylphenoxy)ethoxy]ethoxy]ethoxy]ethoxy]ethoxy]ethoxy]ethoxy]ethoxy]ethanol | 3,6,9,12,15,18,21,24-Octaoxahexacosan-1-ol, 26-(nonylphenoxy)- | 26571-11-9 | NPE |
| 2-[2-(Nonylphenoxy)ethoxy]ethanol | Ethanol, 2-[2-(nonylphenoxy)ethoxy]- | 27176-93-8 | NPE |
| 2-[2-[2-[2-[2-[2-[2-[2-(nonylphenoxy)ethoxy]ethoxy]ethoxy]ethoxy]ethoxy]ethoxy]ethoxy]ethanol | 3,6,9,12,15,18,21-Heptaoxatricosan-1-ol, 23-(nonylphenoxy)- | 27177-05-5 | NPE |

| | | | |
|---|---|---|---|
| 2-[2-[2-[2-[2-[2-[2-[2-[2-[2-(nonylphenoxy)ethoxy]ethoxy]ethoxy]ethoxy]ethoxy]ethoxy]ethoxy]ethoxy]ethanol | 3,6,9,12,15,18,21,24,27-Nonaoxanonacosan-1-ol, 29-(nonylphenoxy)- | 27177-08-8 | NPE |
| 2-(Nonylphenoxy)ethanol | Ethanol, 2-(nonylphenoxy)- | 27986-36-3 | NPE |
| α–(Isononylphenyl)-ω–hydroxy-poly(oxy-1,2-ethanediyl) | Poly(oxy-1,2-ethanediyl), α–(isononylphenyl)-ω–hydroxy- | 37205-87-1 | NPE |
| α–(2-Nonylphenyl)-ω–hydroxy-poly(oxy-1,2-ethanediyl), | Poly(oxy-1,2-ethanediyl), α–(2-nonylphenyl)-ω–hydroxy- | 51938-25-1 | NPE |

**Table 2: NP and NPE Chemical Substances Subject to Reporting Any Use Other Than As An Intermediate Or An Epoxy Cure Catalyst**

| Chemical Name | Chemical Abstracts Index Name | Chemical Abstracts Service Registry No. (CASRN) | NP or NPE |
|---|---|---|---|
| 4-nonylphenol, branched | Phenol, 4-nonyl-, branched | 84852-15-3 | NP |
| 2-nonylphenol, branched | Phenol, 2-nonyl-, branched | 91672-41-2 | NP |

(b) *Specific requirements*. The provisions of subpart A of this part apply to this section except as modified by this paragraph.

(1) *Persons who must report.* Section 721.5 applies to this section except § 721.5(a)(2). A person who intends to manufacture, import, or process for commercial purpose a substance identified in paragraph (a)(2)(i) of this section and intends to distribute the substance in commerce must submit a significant new use notice.

(2) [Reserved]

[FR Doc. 2014-23253 Filed 09/30/2014 at 8:45 am; Publication Date: 10/01/2014]